

REMARKS

Claims 1 and 3 to 22 remain pending. Claim 2 has been canceled.

Claims 1 to 5 have been rejected under 35 U.S.C. 112, second paragraph, for failure to particularly point out and distinctly claim the subject matter regarded as the invention. The Office Action stated that the claims were indefinite because they provide for a use of idebenone without setting forth any steps for a method/process.

The rejection of claims 1 and 3 to 5 under 35 U.S.C. 112, second paragraph, is overcome. Claim 1 as amended requires a method step.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, is moot since it has been canceled.

Claims 1 to 5 have been rejected under 35 U.S.C. 101 as improper process/method claims for failure to set forth any process/method step(s). The rejection of claims 1 to 5 under 35 U.S.C. 101 is overcome. Claim 1 as amended requires a method step.

Claims 6 to 8, 10 to 15, and 18 to 20 have been rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/03657 (U.S. 6,756,045 B1 English equivalent) to Neudecker et al. (Neudecker).

The rejection of claims 6 to 8, 10 to 15, and 18 to 20 under 35 U.S.C. 102(b) over Neudecker is overcome. Claim 1 as amended requires the use of idebenone for the inhibition of melanogenesis, an end use not disclosed in Neudecker. Neudecker discloses idebenone as an antioxidant and free-radical scavenger. Neudecker discloses the topical use of idebenone to prevent skin changes induced by aging, wrinkling, exposure to ultraviolet radiation, degenerative process and oxidation of skin. These uses are related to the antioxidant

properties of idebenone in which the idebenone acts as a scavenger of the free radicals produced by the oxidation of the skin lipids. The present application provides for the use of a topical composition in inhibiting the melanogenesis of the skin, which achieves a reduction of the coloration of the normal skin or depigmentation of the skin in hyperpigmented areas caused by skin disorders. The skin disorders set forth in claim 4 are different from those described in Neudecker.

In the present invention, idebenone has a direct inhibitory effect on the enzyme tyrosinase catalyzing the conversion of tyrosine into melanin. This inhibitory effect is not related to the antioxidant effects described in the art as discussed in the Background in the application. Even though UV exposure can induce skin pigmentation, the specification discloses that topical application of idebenone produces lightening of normal, non-UV exposed human skin. Moreover, topical application of idebenone also depigments the skin of pregnant woman affected by cloasma, a condition that produces skin pigmentation due to hormonal changes. The present application provides a cosmetic and therapeutic use of a topical composition of idebenone directed to treating, as opposed to preventing, the normal and abnormal skin pigmentation of the skin. The mechanism of action disclosed in the application for the idebenone lightening effect/melanin synthesis inhibition is not anticipated or suggested by Neudecker.

Claims 6, 14, 16, and 17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Neudecker as applied to claims 6 to 8, 10 to 15, and 18 to 20 above and further in view of U.S. 5,607,667 B1 to Holcomb (Holcomb).

The rejection of claims 6, 14, 16, and 17 under 35 U.S.C. 103(a) over Neudecker as applied to claims 6 to 8, 10 to 15, and 18 to 20 above and further in view of Holcomb overcome for the reasons set forth above.

Claims 6 and 9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Neudecker as applied to claims 6 to 8, 10 to 15, and 18 to 20 above and further in view of U.S. 2004/0018241 A1 to Houze et al. (Houze).

The rejection of claims 6 and 9 under 35 U.S.C. 103(a) over Neudecker as applied to claims 6 to 8, 10 to 15, and 18 to 20 above and further in view of Houze is overcome for the reasons set forth above.

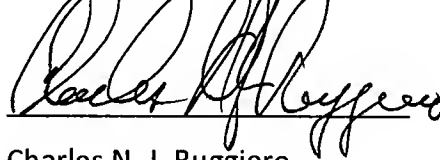
Claims 20 to 22 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Neudecker as applied to claims 6 to 8, 10 to 15, and 18 to 20 above and further in view of U.S. 2002/0192245 A1 to Jensen et al. (Jensen).

The rejection of claims 20 to 22 under 35 U.S.C. 103(a) over Neudecker as applied to claims 6 to 8, 10 to 15, and 18 to 20 above and further in view of Jensen is overcome for the reasons set forth above.

Reconsideration of claims 1 and 3 to 22 is deemed warranted in view of the foregoing, and allowance of said claims is earnestly solicited.

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Respectfully submitted

A handwritten signature in black ink, appearing to read "Charles N. J. Ruggiero", written over a horizontal line.

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